



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1129]

Agency Information Collection Activities; Proposed Collection; Comment Request;

National Agriculture and Food Defense Strategy Survey

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency.

Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for a voluntary survey for the U.S. Department of Health and Human Services (HHS), the U.S. Department of Agriculture (USDA), and the U.S.

Department of Homeland Security (DHS), which will inform the FDA Food Safety Modernization Act (FSMA), National Agriculture and Food Defense Strategy (NAFDS) Report to Congress that is required by April 2019. The proposed survey will be used to determine what food defense activities, if any, State Agencies have completed to date.

DATES: Submit either electronic or written comments on the collection of information by

[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2018-N-1129 for "Agency Information Collection Activities; Proposed Collection; Comment Request; National Agriculture and Food Defense Strategy Survey." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets

Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential."

Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of

information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

National Agriculture and Food Defense Strategy Survey

OMB Control Number--0910-New

We are seeking OMB approval of the NAFDS under FSMA, section 108. This is a voluntary survey of State governments intended to gauge government activities in food and agriculture defense from intentional contamination and emerging threats. The collected information will be included in the mandatory 2019 NAFDS followup Report to Congress. The authority for FDA to collect the information derives from the Commissioner of Food and Drugs' authority provided in section 1003(d)(2)(c) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)(c)).

Protecting the nation's food and agriculture supply against intentional contamination and other emerging threats is an important responsibility shared by Federal, State, local, tribal, and territorial governments as well as private sector partners. On January 4, 2011, the President

signed FSMA. FSMA focuses on ensuring the safety of the U.S. food supply by shifting the efforts of Federal regulators from response to prevention, and recognizes the importance of strengthening existing collaboration among all stakeholders to achieve common public health and security goals. FSMA identifies some key priorities for working with partners in areas such as reliance on Federal, State, and local agencies for inspections; improving foodborne illness surveillance; and leveraging and enhancing State and local food safety and defense capacities. Section 108 of FSMA (NAFDS) requires HHS and the USDA, in coordination with the DHS, to work together with State, local, territorial, and tribal governments-to monitor and measure progress in food defense.

In 2015, the initial NAFDS Report to Congress detailed the specific Federal response to food and agriculture defense goals, objectives, key initiatives, and activities that HHS, USDA, DHS, and other stakeholders planned to accomplish to meet the objectives outlined in FSMA. The NAFDS charts a direction for how the Federal Agencies, in cooperation with State, local, territorial, and tribal governments and private sector partners, protect the nation's food supply against intentional contamination. Not later than 4 years after the initial NAFDS Report to Congress (2015), and every 4 years thereafter (i.e., 2019, 2023, 2017, etc.), HHS, USDA, and DHS are required to revise and submit an updated report to the relevant committees of Congress.

HHS/FDA is primarily responsible for obtaining the information from Federal and State, local, territorial, and tribal partners to complete the NAFDS Report to Congress. An interagency working group will conduct the survey and collect and update the NAFDS as directed by FSMA, including developing metrics and measuring progress for the evaluation process.

The proposed survey of Federal and State partners will be used to determine what food defense activities, if any, Federal and/or State Agencies have completed (or are planning) from

2015 to 2019. Planning for the local, territorial, and tribal information collections will commence after the collection and reporting of Federal and State Agency level data.

This survey will be repeated approximately every 2 to 4 years, as described in section 108 of FSMA, NAFDS, for the purpose of monitoring progress in food and agricultural defense by government agencies.

A purposive sampling strategy will be employed, such that the government agencies participating in food and agricultural defense cooperative agreements with FDA (22 State Agencies) and USDA (27 State Agencies) will be asked to respond to the voluntary survey. Food defense leaders responsible for conducting food defense activities during a food emergency for their jurisdiction will be identified and will receive an emailed invitation to complete the survey online; they will be provided with a web link to the survey. The survey will be conducted electronically on the FDA.gov web portal, and results will be analyzed by the interagency working group.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Survey	49	1	49	0.33 (20 minutes)	16.17

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The total burden for this collection of information, therefore, is 16.17 hours.

The FDA Office of Partnerships reviewed the questionnaire and provided the amount of time to complete the survey. The total burden is based on our previous experiences conducting surveys.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018-06135 Filed: 3/27/2018 8:45 am; Publication Date: 3/28/2018]